Art Unit 2152

Docket No. P-8027.00

associate power of attorney for the undersigned to prosecute the application. Please amend the specification and claims in the application as follows.

In the Specification

Please kindly make the following amendments to the specification.

Page 3, para 2 (once amended). A system permitting the remote communication with a medical device. The system particularly may permit the remote communication such that one or more device experts such as physicians and more experienced device users may be aware of the communication and provide guidance for the subsequent interpretation and programming of the device. The system may include a medical device adapted to be implanted into a patient; a Server Personal Computer (SPC) communicating with the medical device, the SPC having means for transmitting data across a dispersed data communication pathway (Internet); and a client Personal Computer (PC) having means for receiving data transmitted across a dispersed communication pathway from the SPC. In certain configurations the server PC may have means for transmitting data across a dispersed data communication pathway (Internet) along a first channel and a second channel; and the client PC may have means for receiving data transmitted across a dispersed communication pathway from the SPC along a first channel and a second channel. Personal Computer (PC) is a registered trademark of International Business Machines Corporation.

Page 8, para 3 (once amended). As seen, the system has essentially five primary components. Medical device 1 may be of any type which provides therapy to a patient or information collection so long as the device has the ability for communication (uplink

Art Unit 2152

Docket No. P-8027.00

and downlink) to an external device, seen here as programmer 2. Medical device may, for example only and without limitation, comprise a Medtronic Kappa 400 DDDR (Dual paced Dual sensed Dual response to sensing Rate modulation) pacemaker. Programmer 2 may, again, be of any acceptable design which permits linkage to a medical device including the Medtronic 9790 programmer.

Page 10, para 2 (once amended). In the present invention, the second data stream is used for transmission the ECG (Electro Cardio Graph), hence, the UDP data consists of only two bytes per message - one data point of the ECG waveform and its ordinal number. Apart from the ECG waveform, the cardiac therapy device could also send the IEGM, some hemodynamic parameter waveform such as blood pressure, blood flow, or even the ultrasound measurement waveform. UDP can be also used for transmission of the marker channels as well as of the various biochemical sensors signals. For example, within the context where the medical device is a nerve stimulator (similar to the Medtronic Itrel series) the device could transmit a EEG or EGG waveform. In fact, a nerve stimulator having the capability to measure the tremor intensity would transmit the signal representing the tremor intensity thus enabling the DBS (Deep Brain Stimulation) output programming according to the tremor intensity. Since digitized waveforms have an inherent redundancy, in that the general waves are known as well as the possible values of the different parameters, missing data packets or missing data may be quickly identified as being actually missing, as opposed to indicating very low sensed and reported signal strength, or the data having peculiar values. UDP packets are satisfactory for this purpose because it is not crucially important that

Art Unit 2152

Docket No. P-8027.00

every packet arrives. Missing data packets, however, should not normally happen on dedicated network link and therefore this event may be used as an additional test of the network link. That is the amount of missing data packets may be used as a parameter to indicate to the users the fidelity of the link. Such fidelity may be communicated through a pop-up menu or box on one or more of the users screens. This box may indicate that the network transmissions are not complete and that data is missing. Courses of action may thereafter be recommend, including restarting the system, or reissuing the command. It must be understood, however, that other protocols for data transfer may also be used, other than only UDP.

Page 12, para 3 (once amended) FIG. 2A illustrates further details of the possible system embodiment. The server 200 is installed in the remote clinic operated by the technician 201. In this embodiment, programmer 203 having an ECG interface is a separate device and is connected to server 200. Patient 204 is connected by the ECG cable (not shown) to the interface 203 for the purpose of the ECG recording, while programming wand 205 through an electromagnetic coupling enables, as is well know in the medical device field, the communication with the implanted device (not shown). The server 200 is the most complex component of the system, which provides real-time data about the patient's state, accepts and executes the operator's commands, monitors the system's overall performance and reliability, resolves all dubious situations and acts in emergency situations. The server is designed to take all this responsibility because it is nearest to the patient, and failure of any of the components between it and the patient are least likely. It may be a standard PC

Art Unit 2152

Docket No. P-8027.00

computer, but also a "black box" without special screen and command buttons which could confuse the operator 201. A variety of different types of devices may be used to connect server 200 to the Internet (which usually comprises hubs and routers which are not shown) including modem, ISDN or ATM interface 206. A second device is provided to connect client 208 to the Internet. A modem 207 is illustrated as connecting client 208 to the Internet (of course other devices such as ISDN or ATM interface may also be used.) Advisor 209, being the expert for the particular therapy with the medical device, is the operator of the client computer 208. The client 208 shows to the operator 209 a graphic user interface that visually and functionally mimics the GUI of the implantable device programmer 203. It displays the ECG waveform of the patient, and comprises the controls of the ECG recording and display as well as the implantable device programming commands.

Page 15, para 1 (once amended) FIG. 3B is a schematic block diagram of the steps undertaken for the communication with a medical device using the system of the present invention disclosed in FIG. 2B. It is assumed for this illustration that the programmer and the client are a single hardware device. Of course, this is not per se required and separate and discrete devices may also be used. As seen at 3-1, the server is logged into. Thereafter, the server software application is begun at 3-2, whereby server waits for dial-up network connection call. At any time, at 3-3 the patient activates his device and the client application starts at 3-4. Patient puts the programming wand above the implanted device and client identifies medical device through uplinking in identified step, step 3-5. Patient connects the ECG cable to his

Art Unit 2152

Docket No. P-8027.00

body starting to record the ECG waveform at 3-6 supplying the client with the ECG signal at 3-7. At 3-8 client makes a call sending the appropriate request to the server in order to establish the dial-up network connection whereby starting to send a realtime ECG waveform in UDP packets as well as the patient data. As discussed above, this takes place via the Internet using various communication protocols, including TCP/IP. The server identifies the client at 3-9 and the real-time ECG waveform is continuously displayed at 3-10 within the server GUI together with the all of the patient data. Client sends the device identification at 3-11 and server starts the software application for the specific device at 3-12. This causes the change of the GUI at 3-13 bringing display of the additional menus and buttons for interrogation and programming of the specific device. After uplink, device has automatically completed the telemetry measurements at 3-17. Operator of the server points to the appropriate button at 3-14 putting an interrogation and telemetry request at 3-15 to the client through the network which receives and interprets this command at 3-16. As seen, diagnostic memory content and telemetry results are prepared at 3-18 for the processing in order to make a Java applet at 3-19 and to send it via network. The server receives and interprets the applet at 3-20 and displays the telemetry and diagnostics screen at 3-21. This may be the screen such as the QuickLookTM feature of the VisionTM software, the product of the Medtronic, Inc.

Page 16, para 3 (once amended). FIG. 6 depicts the various types of information transferred between client, server and device as well as the protocol used for the transmission.

As discussed above, the system preferably uses at least two communication

Art Unit 2152

Docket No. P-8027.00

channels, the first channel requiring a receipt returned. The second data channel, in contrast, does not provide a receipt that the information was properly received. As seen, the system preferably uses a non-receipt information protocol for information such as the QRS signals (ventricular depolarization) of a pacemaker. Such information is ongoing display information in which the absence of data may be readily ascertained as well as not immediately crucial to device operation.

Other information, such as commands, are transmitted using a protocol in which a receipt of acceptance is provided.

Page 18, para 2 (once amended). FIG. 9 depicts an additional system to the present system. The present system permits communication to be made over dispersed mediums such as an internet. As such it permits ready access by a multiple number of clients to a single server. Thus, as seen, the system could permit, in addition to client A, depicted here as 4 (and which is communicated with and to in the same manner as that discussed with regards to FIG. 1), the additional provision of client B 9-2 and client C 9-3. These additional clients may have varying means of access to the server and, thus, to the programmability of the device. For example, client B may have access to be only an observer while client C may be provided to be an observer/client with the additional ability to interrogate the device as well as do memory and telemetry read out. In this environment, moreover, server 3 plays a more active role. For example, as discussed above each client may have various level of access. To permit this, server 3 provides differing GUI applets to the differing authorized clients. For example, only one authorized client would have the possibility to control the

Art Unit 2152

Docket No. P-8027.00

programming session i.e. program the therapy device and to see the private patient data. Other clients would only have the possibility to observe what is the authorized client doing. They could also save the interrogated program and telemetry data as well as the ECG, IEGM (Intracardiac ElectroGraM) and marker channel waveforms in their computers for the later recall for the education purpose.

Page 21, para 1 (once amended). ATM brings completely new possibilities for telemedicine and particularly for the implantable devices follow-up. IP over ATM will be the most important variant of the infrastructure utilized for the public network. ATM is a connection-oriented technology utilizing the Layer 2 cell switching of the Open Systems Interconnection protocol that is the hardware based. In contrary to that, IP is a connectionless protocol whereby IP networks use software-based Layer 3 packet routing. From the practical point of view, the most convenient for teleprogramming would be the ATM connection between the client and the server, despite of the fact which one of the two comprises the programmer. It may happen that commercial interest will rise among the medical institutions and small physicians offices in such a manner that they will have multiple tasks and therefore cheap ATM connection for teleradiology, telepathology, teleconference, telesurgery and other various telemedicine applications. Nevertheless, several IP over ATM protocols are in development. Particularly the Internet Engineering Task Force (IETF) has been active developing the RFC 1577 being the first true IP over ATM technology called Classical IP (CLIP) and emulating the IP subnetwork in an ATM infrastructure. One or more logical internetworking subnetworks are connected to a backbone subnetwork